UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,592	03/11/2004	Robert A. Herrmann	00-0193 D1	6360

27774 7590 11/01/2007

MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,592	HERRMANN ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 8/22/07.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) 23-39 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 03/11/2004.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' election and amendment, both filed 08/22/2007; and IDS filed 03/11/2004.

1. Applicant's election without traverse of invention I, species vascular medical devices, S-nitrosylated compounds, nitroso-N-acetyl-pencillamine, S-nitrosoglutathione, claims 1-22, in the reply filed on 08/22/2007 is acknowledged.

2. Claims 23-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 08/22/2007.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recite single first nitric oxide donor (NO) compound and single second nitric oxide donor compound in the 2nd and 3rd lines of the claims, however, the claim recites that "one or more of said nitric oxide donor compound" in the 6th and 8th lines of the claim. If it is one compound is recited, then how one or more compound will be delivered?

Claim 1 recites the limitation "product" in the 7th and 9th lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 recites that the first NO compound has a short half-life and the second NO donor has a long half-life, while claim 8 recites the opposite fact that the first NO donor has half life that is at least 10 times greater than the second NO donor.

Claim 9 recites the limitation "vasculature" in the 2nd line of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,287285 ('285) combined with the article "S-Nitrosothiols cause prolonged, nitric oxide mediated relaxation in human saphenous vein and internal mammary artery: therapeutic potential in bypass surgery" by Sogo et al.

US '285 teaches medical device inserted into the vasculature of patient such as cardiac leads comprising nitric oxide (NO) donating compounds incorporated in solution or polymer (abstract; col.2, lines 28-31; col.5, lines 8-15; col.19, claim 14). The NO compounds include one or more NO donor compounds selected from the group containing of S-nitroso-N-acetyl-D,L-penicillamine and S-nitrosoglutathione (col.20, claim 20). Therapeutic agents can be included in the device including amino acids (col.4, line30).

Although the reference suggested inclusion of more than one NO donor in the medical device and disclosed 7 preferred members of NO donors included S-nitroso-N-acetyl-D,L-penicillamine and S-nitrosoglutathione, however, the reference does not explicitly teach the combination of S-nitroso-N-acetyl-D,L-penicillamine and S-nitrosoglutathione.

Sogo et al. teach that S-nitroso-N-acetyl-D,L-penicillamine and S-nitrosoglutathione produce more relaxation of vessel walls than commonly used NO donors, and more specifically, teach that the relaxation caused by S-nitroso-N-acetyl-D,L-penicillamine was more sustained, and S-nitrosoglutathione selectively dilates human arteries in vitro and in vivo, and their use might improve the outcome of coronary artery bypass (page 1237, left col.; page 1241, right col.; page 1243, left col.).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide medical device for vascular use comprising more than one NO donor compounds as disclosed by US '285, and select S-nitroso-N-acetyl-D,L-penicillamine and S-nitrosoglutathione from the group of 7 NO donors disclosed by US '285, motivated by the teaching of Sogo et al. that these two NO donor compounds produce more relaxation of vessel walls than commonly used NO donors with prolonged sustained relaxation and dilatation of human arteries, and their use might improve the outcome of coronary artery bypass, with reasonable expectation of having medical device for vascular use comprising S-nitroso-N-acetyl-D,L-penicillamine and S-nitrosoglutathione that successfully provides prolonged sustained relaxation and dilatation of human arteries, with improvement on the outcome of coronary artery bypass.

The combination of the references teaches the same first nitric oxide donor and second nitric oxide donor as instantly claimed, therefore, the half-life, activity, release rates, and susceptibility to metal ion catalyst release are expected to be the same as those recited by the instant claims.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6,706,274. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims and the patented claims are directed to common subject matter drawn to medical article comprising first nitric oxide donor and second nitric oxide donor wherein the first and second NO donors are not the same, and the patented claims anticipate the present claims.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

IG

ISIS GHALI
PRIMARY EXAMINER